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EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3773

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/611,551	Applicant(s) SHELSON, SUSAN I.	
	Examiner Melanie Tyson	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13, 16-24, 26, 27, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13, 16-24, 26, 27, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 22 January 2008.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

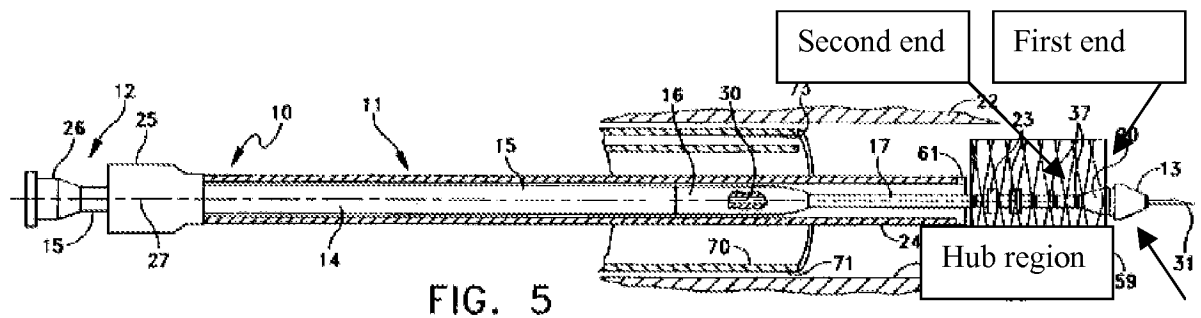
2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 11-13, 16-24, 26, 27, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft (Patent No. 5,702,418). Ravenscroft discloses a stent delivery system (see entire document) comprising a catheter having an inner shaft (31), a retractable sheath (24), at least one radiopaque grip member (for example, see column 7, lines 42-45) having a substantially tapered body region (tapered portion of 13) and a hub region (enlarged portion of 13) having an outer diameter greater than the outer diameter of the first end of the body region, and an expandable stent (20) comprising a plurality of struts disposed about the inner shaft and engaged to at least a portion of the body region, wherein during use, the hub region is positioned proximal to

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the stent (20), and the outer diameter of the hub region is greater than the outer diameter of the stent (20) when the stent (20) is in an unexpanded state (for example, see Figures 1, 4, 5, and illustration below).



Ravenscroft fails to disclose that during use the stent directly contacts the hub region. However, the applicant discloses that during use, the stent may be positioned adjacent to or butted up against an inner surface of the hub (for example, see page 5, lines 11-12 and Figures 6 and 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to situate the stent such that it directly contacts the hub region during use as a matter of design choice, since the applicant has not disclosed that this configuration provides an advantage, is used for a particular purpose, or solves a stated problem and it appears the prior art stent positioned adjacent to the hub region would perform equally well as a stent directly contacting the hub.

With further respect to claim 13, the grip member disclosed by Ravenscroft is inherently capable of reducing the longitudinal force the catheter exerts on the struts,

since the grip member reduces the potential space between the inner catheter shaft and the retractable sheath.

With further respect to claims 16-18, Applicant fails to disclose that utilizing a second grip member provides an advantage, is used for a particular purpose, or solves a stated problem over utilizing a single grip member. Applicant further discloses that a single grip member may be used in the delivery system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a second grip member, since it has been held that a mere duplication of the essential working parts involves only routine skill in the art.

With further respect to claims 21, 26, and 27, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the grip member of a polymeric material, such as polyether block amides, since polymeric materials are well known in the art in order to reduce the risk of kinking of devices inserted into the vascular system (for example, see column 5, lines 23-30) and it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use.

With further respect to claims 19 and 20, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the grip with a hardness of about 60 to about 90, or of 70 to about 90, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Response to Arguments

4. Applicant's arguments filed 22 January 2008 have been fully considered but they are not persuasive. Applicant argues primarily that the prior art applied fails to disclose, suggest, or teach each and every element claimed. Examiner respectfully disagrees.

Applicant argues that Ravenscroft fails to disclose a hub region that is “positioned **proximal** to the stent.” Claims in a pending application should be given their broadest reasonable interpretation. The term “proximal” has been interpreted as being “situated close to” (for example, see Merriam-Webster Online Dictionary), in that the hub region is situated close to the stent, and Ravenscroft discloses the configuration as claimed (for example, see Figures 1 and 5). Applicant further argues that Ravenscroft fails to disclose the stent directly contacts the hub region, however, such a modification would have been obvious as a matter of design choice (see new rejection above). With respect to applicant's argument that it would not be physically possible to place both Ravenscroft's stent and his outer sheath in abutment with the hub region, Ravenscroft does not disclose that the sheath abuts the hub region's entire inner surface or any portion thereof. Applicant cites Figure 1, however, Figure 1 illustrates that the sheath engages the outermost portion of the hub region with a space between the outermost portion and the inner portion of the inner surface. Since the stent has a diameter smaller than the sheath during use, it is physically possible for the stent to directly contact an inner portion of the inner surface of the hub region while the sheath engages the outermost portion of the hub region as illustrated.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
May 1, 2008

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773